

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Morris Samelson and

Johnathan M. Scharff

Serial No.:

10/601,796

Filed:

June 23, 2003

For:

Ultra Fine Dead Sea Mineral Compound and Method of Manufacture

Group No.:

1615

Examiner:

Lakshmi Sarada Channavajjala

### CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop: RESPONSE/FEE Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia, on August 23, 2007.

MORKIS SAMELSON

(Printed or typed name of person signing the certificate)

(Signature of the person signing the certificate)

### DECLARATION OF PRIOR INVENTION IN THE UNITED STATES TO OVERCOME CITED PATENT OR PUBLICATION (37 C.F.R. § 1.131)

- 1. This declaration is to establish completion of the invention of the above referenced United States Patent application ("Application") in the United States at a date before May 7, 2001, the earliest priority date of prior art application serial US 2003/0211062 ("Laden") that was cited by the Examiner.
  - 2. The person making this declaration is the inventor.

### Facts and documentary evidence

- 3. To establish a date of conception of the invention of this application before the priority date of Laden, the following attached documents are submitted as evidence, all of which are true copies of the originals:
  - (i) Manufacturing Batch Record Compounding Module dated February 2, 2001.
  - (ii) Manufacturing Batch Record Milling Module dated February 1, 2001.
  - (iii) Photos of the finished product PharmaSea® Dead Sea Mineral Scrub showing front and back silk screened labeling as well as product lot number stamped into tube corresponding to date of manufacture.
  - (iv) Drawings summarizing invention dated December 2006.
- 4. Laden is a national stage entry of application No. PCT/US01/14570 which was filed on May 7, 2001 and claims priority to an earlier filed provisional application 60/202,409 which fails to disclose the present invention found in Application. Laden was published on November 13, 2003. Laden teaches anhydrous skin cleansers with abrasive materials. The divisional Application was filed on June 23, 2003 and claims priority to filing date August 16, 2001 less than four months after Laden's earliest priority filing date of May 7, 2001.
  - 5. The Applicant avers the following:
  - (a) Applicant conceived the invention before February 2, 2001;
- (b) For a period of approximately one year prior to August of 2000 we had experimented extensively with selected natural ingredients and attempted to include the native Dead Sea minerals but were unable to find a suitable formulation due to the larger granules sizes. Extensive research and development utilizing processed ultra fine Dead Sea minerals (salts) was carried out during the six months prior to January of 2001 in order to develop the processor necessary to process native Dead Sea minerals into ultra fine Dead Sea minerals as novel commercially viable raw material ingredients for esthetically acceptable formulations. The

purpose of the final experimentation in January 2001 (for which charts have been previously submitted to file) was to re-evaluate our findings and determine the final formula best suited as our consumer product PharmaSea® Dead Sea Mineral Scrub product which includes our processed ultra fine Dead Sea minerals having granularity 100% less than 1 mm.

- (e) The Application was filed on June 23, 2001 and is a divisional of application 09/931,453 filed on August 16, 2001.
- 6. From these documents and photos, it can be seen that the invention in the Application was reduced to practice by February 2, 2001 which is earlier than the priority date of Laden.
- 7. The foregoing also establishes the diligence of the Applicant, from the time of conception to the time of constructive reduction to practice.
- 8. Information of further relevance was included in and attached to my previous Declaration under 37 C.F.R. § 1.132 dated January 16, 2007 and submitted to file.
- 9. This declaration is submitted in response to an office action in which Examiner relied on Laden as a reference.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Morris Samelson

Date

AUGUST 23,2007

## COMPOUNDING MODULE

ISSUED

(c) Preparation

( Formula Page

(J Bulk Compounding

REVIEWED

( ) Preparation

(\*) Formula Page (\*) Bulk Compounding

> Issued By: Monnis Samecson Date: 02/02/01

Reviewed By: Johnathan A. Schanff Date: 02/02/61

PharmaSea® Dead Sea Mineral Scrub Page: Of: Module: Compounding Product Name: Date: 02/02/01 Date: 02/12/0/ Approved By: Prepared By:

Earth Salts International Inc. Manufacturing Batch Record

Date of Manufacture: February 2, 2001

|              | PREPARATION                                                                                                                                                                           | Performed By:                            | Verified By: |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|--------------|
| ij           | Equipment Required                                                                                                                                                                    |                                          |              |
|              | <ul> <li>a. Primary compounding vessel:</li> <li>Scott Turbon Mixer (triple motion processor), 200 gal.</li> <li>b. Swift Heating System</li> <li>c. Swift Chilling System</li> </ul> |                                          |              |
| Ħ            | Preliminary Work  a. Batch DOES NOT require QA release prior to filling. Use Yellow Tank Card System.                                                                                 |                                          |              |
| II.          | Safety Precautions  a. Eye protection must be worn during entire manufacturing process.                                                                                               | S M                                      | SM           |
| `            | THE ABOVE SAFETY PRECAUTIONS HAVE BEEN READ, UNDERSTOOD, SIGNED AND DATED BELOW:    H. Shall   O2   02   02   01   01   01   01   01   0                                              |                                          |              |
| Prepared By: | WS,                                                                                                                                                                                   |                                          |              |
| Apployed by. | PharmaSea® Dead Sea Miner                                                                                                                                                             | Lot Code: 20201<br>(corresponds to date) |              |

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| De la Car    | [≥                                  | anulacturing Batch Record | Kecord            | <b>a</b> | ate of Manu       | Date of Manufacture: February 2, 2001 | uary 2, 2001                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------------|-------------------------------------|---------------------------|-------------------|----------|-------------------|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Number       | Description                         | M/M%                      | Control<br>Number | Amount   | Amount<br>Weighed | Performed By:                         | Checked<br>Bv:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|              | Salt Phase                          |                           |                   |          |                   |                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 2001         | Processed ULTRA FINE Dead Sea Salts | 51.00                     |                   | 816 Lb   | 0                 | 2 N                                   | DW                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|              | Oil Phase                           |                           |                   |          |                   |                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 1001         | Palm oil                            | 25.00                     |                   | 400 Lb   | 700               | /NS                                   | N. S.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 1002         | Soybean oil                         | 9.00                      |                   | 144 Lb   | nhl               | MS                                    | Z                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 1003         | Olive oil                           | 5.00                      |                   | 80 Lb    | 0                 | MS                                    | · ·                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1004         | Jojoba oil                          | 3.00                      |                   | 48 Lb    | 2                 | SM                                    | 7                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 1005         | Beeswax                             | 3.00                      |                   | 48 Lb    | 2                 | MS                                    | V                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 1006         | Jojoba wax PEG 120                  | 1.00                      |                   | 16 Lb    | 97                | CM/                                   | S M                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1007         | Cashew husk oil ethoxylate (Clarit) | 1.00                      |                   | 16 Lb    | 91                | M                                     | 54                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 1008         | Coconut oil                         | 1.00                      |                   | 16 Lb    | 91                | ME                                    | \\ \times \\ \ti |
| 1009         | Vitamin E oil (Covitol 1250)        | 1.00                      |                   | 1.6 Lb   | 9.1               | MS                                    | N N                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 1010         | Vitamin E oil (Covi-ox)             | 0.05                      |                   | 0.8 Lb   | 8.0               | SW                                    | 7                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|              |                                     |                           |                   |          |                   |                                       | \<br>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|              |                                     |                           |                   |          |                   |                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Prepared By: | Module: Compounding                 | Page:                     | Of: Section:      |          | Page: Of:         | Document No.                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Approved By: | Mane: Product Name: PharmaSea®      | Dead S                    | Mineral Sc        | hin      | 7                 | Lot Code: 20201                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|              |                                     |                           |                   | 777      |                   |                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

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| Earth Salt     | Earth Salts International Inc. Manufacturing Batch Record | ing Batch        | 1 Record                                        | Д                   | ate of Manu       | Date of Manufacture: February 2, 2001    | uary 2, 2001                           |
|----------------|-----------------------------------------------------------|------------------|-------------------------------------------------|---------------------|-------------------|------------------------------------------|----------------------------------------|
| Part<br>Number | Description                                               | M/M%             | Control<br>Number                               | Amount              | Amount<br>Weighed | Performed<br>By:                         | Checked<br>Bv:                         |
|                | Fragrance Phase (essential oil blend)                     |                  |                                                 |                     |                   | •                                        |                                        |
| 1012           | Rosewood Oil                                              | 0.44             |                                                 | 7.04 Lb             | 7.04              | SI                                       | ) H                                    |
| 1013           | Lavender Oil                                              | 0.34             |                                                 | 5.44 Lb             | × 22.             | SM                                       | \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ |
| 1014           | Chamomile Oil                                             | 0.20             |                                                 | 3.20 Lb             | 3.20              | 145                                      | \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\ |
| 1015           | Calendula Oil                                             | 0.02             |                                                 | 0.32 Lb             | 6.32              | MS M                                     | \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ |
|                |                                                           |                  |                                                 |                     |                   |                                          |                                        |
|                |                                                           |                  |                                                 |                     |                   |                                          |                                        |
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|                |                                                           |                  |                                                 |                     |                   |                                          |                                        |
|                |                                                           |                  |                                                 |                     |                   |                                          |                                        |
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|                |                                                           |                  |                                                 |                     |                   |                                          |                                        |
|                |                                                           |                  |                                                 |                     |                   |                                          |                                        |
|                |                                                           |                  |                                                 |                     |                   |                                          |                                        |
|                |                                                           |                  |                                                 |                     |                   |                                          |                                        |
| Prepared By:   | MS Module:                                                | Page:<br>ding 4  | Of:                                             | Section:<br>Formula | Page: Of:         | Document No.<br>C001 001 00              |                                        |
| Approved By:   | Product Name: PharmaSea@                                  | ne:<br>a® Dead S | Product Name: PharmaSea® Dead Sea Mineral Scrub | Scrub               |                   | Lot Code: 20201<br>(corresponds to date) | ate)                                   |
|                |                                                           |                  |                                                 |                     |                   |                                          |                                        |

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Manufacturing Batch Record

Batch Record Date of Manufacture: February 2, 2001

|                                                                                                 | BULK COMPOUNDING                                                                                                                                                            | Ľ.                                      |                                            | Performed By:   | Verified By: |
|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------------------------------------|-----------------|--------------|
| I. Oil Phase:                                                                                   | 1                                                                                                                                                                           |                                         |                                            |                 |              |
|                                                                                                 |                                                                                                                                                                             |                                         |                                            |                 |              |
| <ul><li>a. Add to the Primary</li><li>Turn on heating sys</li><li>Heat contents to 65</li></ul> | Add to the Primary Compounding Vessel when temp reaches 35°C; Turn on heating system and open flow through jacket in vessel. Heat contents to 65°C while mixing slow speed. | en temp reach<br>h jacket in ves<br>ed. | es 35°C;<br>ssel.                          |                 |              |
| Palm Oil                                                                                        |                                                                                                                                                                             | 400 Lb                                  | d,                                         | SAN SAN         | ~ =          |
| Beeswax                                                                                         |                                                                                                                                                                             | 48 Lb                                   | ,b d.                                      |                 | •            |
| Jojoba Wax PEG 120                                                                              | 20                                                                                                                                                                          | 16 Lb                                   | 4<br>2                                     |                 |              |
| Beeswax                                                                                         |                                                                                                                                                                             | 48 Lb                                   | , d.                                       |                 |              |
| Cashew Husk Oil Exthoxylate (Clarit)                                                            | Exthoxylate (Clarit)                                                                                                                                                        | 16 Lb                                   | <b>5</b>                                   |                 |              |
|                                                                                                 |                                                                                                                                                                             |                                         |                                            |                 |              |
| Prepared By: MCS                                                                                | Module:<br>Compounding                                                                                                                                                      | Page: Of:                               | Section: Page: Of:<br>Bulk Compounding 1 4 | Document No.    |              |
| Approved By: NA 5                                                                               | Product Name: PharmaSea® Dead Sea Mineral Scrub                                                                                                                             | ead Sea Mine                            |                                            | Lot Code: 20201 |              |

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Manufacturing Batch Record

Date of Manufacture: February 2, 2001

| BULK COMPOUNDING-cont'd                                                                                                                                                                                                      | Performed By:                           | Verified By:                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|-----------------------------------------|
|                                                                                                                                                                                                                              |                                         |                                         |
| b. When a. reaches 65°C and is completely melted together increase mixing with high speed agitation and add:                                                                                                                 | - dg                                    | ,                                       |
| ADDED                                                                                                                                                                                                                        | SM                                      | 5                                       |
| Soybean oil 144.0 Lb (                                                                                                                                                                                                       |                                         |                                         |
| Olive oil 80.0 Lb                                                                                                                                                                                                            | • • • • • • • • • • • • • • • • • • • • |                                         |
| Jojoba oil 48.0 Lb (                                                                                                                                                                                                         |                                         |                                         |
| Covitol 1250 1.6 Lb (                                                                                                                                                                                                        |                                         | *************************************** |
| Covi-ox 0.8 Lb (                                                                                                                                                                                                             |                                         |                                         |
| Increase speed of scrape surface agitation and triple impellor to medium. Turn off heating system and close off flow of hot water to jacket of vessel. Turn on Turbon (turbine) for high speed homogeneous mixing/agitation. |                                         |                                         |
| OIL PHASE COMPLETED                                                                                                                                                                                                          |                                         |                                         |
| II. Salts Phase:                                                                                                                                                                                                             |                                         |                                         |
| a. Add ULTRA FINE Dead Sea Salts and continue higher speed mixing:                                                                                                                                                           |                                         |                                         |
| ULTRA FINE Dead Sea Salts 816.00 Lb                                                                                                                                                                                          |                                         | 4                                       |
|                                                                                                                                                                                                                              | MS                                      |                                         |
| MeS                                                                                                                                                                                                                          | of: Document No. 2 4 C001.001.00        |                                         |
| Approved By: \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\                                                                                                                                                                             |                                         |                                         |
|                                                                                                                                                                                                                              |                                         |                                         |

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| Performed By: Verified By: |                                                                                 |                |                        | YIELD                        |                                        | .62_Lb                                                                                                                               |                                                    | IV.   MS   NS       |              |                                         | V. MS 1            |              | o ;       | . Of:                   | 4 4 4                   | 4 4<br>4                | . Of:                            | . Of:                            | . Of:                            |
|----------------------------|---------------------------------------------------------------------------------|----------------|------------------------|------------------------------|----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------|---------------------|--------------|-----------------------------------------|--------------------|--------------|-----------|-------------------------|-------------------------|-------------------------|----------------------------------|----------------------------------|----------------------------------|
| BULK COMPOUNDING-cont'd    | GROSS: $\frac{ \phi _{\sigma^{\mathcal{D}}}}{ \phi _{\sigma^{\mathcal{D}}}}$ Lb | TARE: 15 62 Lb | NET WEIGHT: 1584,38 Lb | 584.3/Lb x 100<br> 1600.0 Lb | Calculate and record Compounding loss: | ( $ \theta00 \text{ Lb}\rangle - (\text{Net Weight: }  594.34 \text{ Lb}\rangle = \text{Compounding Loss: }  5.62 \text{ Lb}\rangle$ | 97-103%. If outside this range, notify supervisor. | PHASE IV. COMPLETED |              | ce samples to QA.                       | PHASE V. COMPLETED | 30           | rage: OI: | rage: Or:<br>unding 8 8 | rage: Or:<br>unding 8 8 | rage: OI:<br>unding 8 8 | rage: OI:<br>unding 8 8<br>lame: | rage: OI:<br>unding 8 8<br>vame: | rage: OI:<br>unding 8 8<br>vame: |
| N. Reconciliation          | a. Weigh and record:                                                            |                | <b>~</b>               | Net Weight: 15               | b. Calculate and reco                  | (   600 Lb) – (Net Wei                                                                                                               | NOTE: Yield limits are 97-103%.                    |                     | VI. Sampling | a. Submit two four ounce samples to QA. |                    | Prenared Rv. | SIM       | JUS S                   | A Month                 | Annroved By:            | Approved By:                     | Approved By:                     | Approved By:                     |

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# (ATMOSULTRAMILL) MILLING MODULE

**ISSUED** 

(

Description Pages

(S) Bulk Milling

REVIEWED

(\*) Preparation

(v) Description Pages

 $(\nu)$  Bulk Milling

Issued By: MORKIS SAMELSON

Date: 02/01/01

Reviewed By: Johnstonn H. Schneff Date: 02/01/01

Processed ULTRA FINE Dead Sea Minerals (salts) Page: Raw Material Name: Milling Module: Date: 02 [01]0] Date: 02/01/01 Approved By: Prepared By:

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Manufacturing Batch Record

Date of Manufacture: February 1, 2001

|                           | PREPARATION                                                                                                                                                                                                                                                                      | Performed By:                                                | Verified By: |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|--------------|
| ï                         | Equipment Required                                                                                                                                                                                                                                                               |                                                              |              |
|                           | <ul> <li>a. Primary milling system:</li> <li>Modified Conical Screen Mill</li> <li>b. Hapman infeed conveyor (infeed to milling system)</li> <li>c. Hapman outfeed conveyor (for drum fill on weigh scale)</li> <li>d. Dust control system, Metler floor scale, wench</li> </ul> |                                                              |              |
| H H                       | Preliminary Work  a. Batch DOES NOT require QA release prior to milling.  Safety Precautions                                                                                                                                                                                     | SA                                                           | 5            |
|                           | a. Eye protection must be worn during entire manufacturing process. Dust control system must be attached and activated prior to and during milling process. All electric controls to be checked prior to plug in of systems with all switches in off position.                   |                                                              |              |
|                           | THE ABOVE SAFETY PRECAUTIONS HAVE BEEN READ, UNDERSTOOD, SIGNED AND DATED BELOW:    Windle                                                                                                                                                                                       |                                                              |              |
| Prepared By: Approved By: | W: M. Section: Page: Of: Section: Page: Of: Milling 2 7 Preparation 1 1  By: M. Processed ULTRA FINE Dead Sea Minerals (salts)                                                                                                                                                   | Document No.  M001.001.00  Lot Code: 20101AUM (Include date) | MU           |

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| Earth Salt     | Earth Salts International Inc. Manufacturing Batch Record                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | tch Record                                               | De                                              | ite of Manu                            | Date of Manufacture: February 1, 2001                  | nary 1, 2001                  |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|-------------------------------------------------|----------------------------------------|--------------------------------------------------------|-------------------------------|
| Part<br>Number | Description of processed raw material produced in house                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                          | Amount<br>needed                                | Amount<br>Weighed                      | Performed<br>By:                                       | Checked<br>By:                |
|                | PROCESSED RAW MATERIAL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                          |                                                 | )                                      |                                                        |                               |
| 2001           | (Processed) ULTRA FINE Dead Sea<br>Salts                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                          | 910 Lb                                          | 906                                    | SMP                                                    | 5                             |
|                | Size: 100% less than 1 mm and 10 mesh<br>US Sieve unit.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                          |                                                 |                                        |                                                        |                               |
|                | Suitable for use in manufacturing products that require scrubbing effect as well as those that do not require scrubbing effect. (Grade 1)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                          |                                                 |                                        |                                                        |                               |
|                | Action: 910 Lb native Dead Sea minerals (salts) processed through proprietary ATMOSULTRAMILL system with modified room atmosphere with temperature 75°F with cool dry positive pressure. RPM 4800. Material Choke fed. Native Dead Sea Salts have been processed into ULTRA FINE Dead Sea Salts. Native Dead Sea Salts information attached including Typical Analysis.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | rocessed through<br>with cool dry part.<br>JLTRA FINE De | n proprietary<br>ositive pressi<br>ad Sea Salts | ATMOSUL<br>re. RPM 480<br>. Native Dea | TRAMILL syste<br>00. Material Cho<br>d Sea Salts infor | em with<br>oke fed.<br>mation |
| Prepared By:   | Module: P. Milling                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Page: Of: Section:                                       | doit                                            | Page: Of:                              | Document No.                                           |                               |
| Approved By:   | Raw Material Name:  Processed UT TRA FINE Dead Sea Minerals (salts)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | A FINE Dead Se                                           | Minerals (                                      |                                        | Lot Code: 20101AUM                                     | AUM                           |
|                | MANAGE NAMES OF THE PARTY NAMES | 77 TILL TYCH UX                                          | יו כושוקווואאן ש                                | Salls                                  |                                                        |                               |

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| Earth Salt     | Earth Salts International Inc. Manufacturing Batch Record                                                                                                                                                                                                                                                                                                                                       |                                                                   | Date of Manu                               | Date of Manufacture: February 1, 2001                  | uary 1, 2001                      |
|----------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|--------------------------------------------|--------------------------------------------------------|-----------------------------------|
| Part<br>Number | Description of processed raw material produced in house                                                                                                                                                                                                                                                                                                                                         | Amount                                                            | Amount<br>Weighed                          | Performed<br>By:                                       | Checked<br>By:                    |
|                | PROCESSED RAW MATERIAL                                                                                                                                                                                                                                                                                                                                                                          |                                                                   |                                            |                                                        |                                   |
| 2002           | (Processed) ULTRA FINE Dead Sea<br>Salts                                                                                                                                                                                                                                                                                                                                                        | 110 Lb                                                            | 801                                        | SM                                                     | 71                                |
|                | Size: 100% Less than 1 mm and 10 mesh<br>US Sieve unit.                                                                                                                                                                                                                                                                                                                                         |                                                                   |                                            |                                                        |                                   |
|                | Suitable for use in manufacturing products that require scrubbing effect as well as those that do not require scrubbing effect. (Grade 2)                                                                                                                                                                                                                                                       |                                                                   |                                            |                                                        |                                   |
|                | 110 Lb native Dead Sea minerals (salts) processed through proprietary ATMOSULTRAMILL system with modified room atmosphere with temperature 75°F with cool dry positive pressure. RPM 4800. Change part for finer material. Material choke fed. Native Dead Sea Salts have been processed into ULTRA FINE Dead Sea Salts. Native Dead Sea Salts information attached including Typical Analysis. | gh proprietary ATM<br>ositive pressure. RPI<br>ocessed into ULTRA | OSULTRAMI<br>M 4800. Chang<br>FINE Dead So | LL system with<br>e part for finer<br>ea Salts. Native | modified<br>material.<br>Dead Sea |
| Prepared By:   | Module: Page: (                                                                                                                                                                                                                                                                                                                                                                                 | Of: Section: 7 Description                                        | Page: Of:                                  | Document No.                                           |                                   |
| Approved By:   | Raw Material Name:<br>  Processed ULTRA FINE Dead Sea Minerals (salts)                                                                                                                                                                                                                                                                                                                          | E Dead Sea Minerals                                               |                                            | Lot Code: 20101AUM                                     | AUM                               |
|                |                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                   |                                            |                                                        |                                   |

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Manufacturing Batch Record

Earth Salts International Inc.

|                         | BUL                                                                                                                                                                                                                                                                                                                                                                  | K MILLING                                                                                       |                                                                                                                       |                                      | Performed By:      | Verified By: |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|--------------------------------------|--------------------|--------------|
| Grade 1:                |                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                 |                                                                                                                       |                                      |                    |              |
| ï                       | Connect Hapman conveyors to mod. conical screen mill with attached dust control and Metler floor scale for weigh activated filling of fiber drums with 4 mil inner liner bags (lock tied) forming ATMOSULTRAMILL: Activate system (turn on all components) and begin adding native Dead Sea Salts to in-feed hopper as needed to maintain steady fill rate on drums. | s to mod. conica<br>ale for weigh act<br>forming ATMO:<br>I components) a<br>I to maintain stea | Il screen mill with attache ivated filling of fiber drus SULTRAMILL: nd begin adding native Deady fill rate on drums. | ed dust ims with 4 mil ead Sea Salts | Sm                 |              |
| {Typica                 | Native Dead Sea Salts {Typical Analysis - description attached}                                                                                                                                                                                                                                                                                                      | ached}                                                                                          | 910.0Lb                                                                                                               |                                      |                    |              |
| Fill and<br>Scrub p     | Fill and stack drums in warehouse for utilization in PharmaSea® Dead Sea Mineral Scrub product manufacturing on 02/02/01.                                                                                                                                                                                                                                            | for utilization in<br>2/02/01.                                                                  | PharmaSea® Dead Sea                                                                                                   | Mineral                              |                    |              |
| CLEAN SYSTEM THOROUGHLY | THOROUGHLY                                                                                                                                                                                                                                                                                                                                                           | Grad                                                                                            | Grade 1 run COMPLETED                                                                                                 | Ï                                    |                    |              |
| Grade 2:<br>II.         | Change parts for finer grade ULTRA FINE and repeat II and utilize existing setup of I with change part for finer flour like material.  ADDED                                                                                                                                                                                                                         | e ULTRA FINE<br>Ier flour like mat                                                              | and repeat II and utilize e)<br>terial.<br><u>ADDED</u>                                                               | existing setup                       |                    |              |
| {Typic:                 | Native Dead Sea Salts {Typical Analysis - description attached}                                                                                                                                                                                                                                                                                                      | ached}                                                                                          | 110.00 Lb                                                                                                             | \ <u></u>                            |                    |              |
|                         |                                                                                                                                                                                                                                                                                                                                                                      | Grade                                                                                           | Grade 2 run COMPLETED                                                                                                 | II.                                  |                    |              |
|                         |                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                 |                                                                                                                       |                                      | MS                 | X            |
| Prepared By:            | S                                                                                                                                                                                                                                                                                                                                                                    | Module:<br>Milling                                                                              | Page: Of: Section:                                                                                                    | Page: of:                            | Document No.       |              |
| Approved By:            | 5                                                                                                                                                                                                                                                                                                                                                                    | Product Name:<br>Processed ULTR                                                                 | 6                                                                                                                     |                                      | Lot Code: 20101AUM | M            |

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| RII K MII I INC. cont'd                                                                 | Performed By:      | Verified By: |
|-----------------------------------------------------------------------------------------|--------------------|--------------|
| -'I                                                                                     |                    |              |
| III. Reconciliation: Grade 1                                                            |                    |              |
| a. Weigh and record: GROSS: 9/0 Lb                                                      |                    |              |
| TARE: 4 Lb                                                                              |                    |              |
| NET WEIGHT: 906 Lb                                                                      |                    |              |
| Net Weight: 906 Lb x 100 = 949.56 % YIELD                                               |                    |              |
| b. Calculate and record Milling loss:                                                   |                    |              |
| ( $^{0}$ ( $^{0}$ Lb) – (Net Weight: $^{0}$ $^{0}$ $^{0}$ Lb) = Milling Loss: $^{0}$ Lb |                    |              |
| NOTE: Yield limits are 97-103%. If outside this range, notify supervisor.               | (                  | (            |
| COMPLETEDIII.                                                                           | MIS                | 5            |
| IV. Sampling                                                                            |                    |              |
| a. Submit two four ounce samples to QA.                                                 | ί.                 | (            |
| COMPLETEDIV.                                                                            | - (M)              | 5            |
| Prepared By: MS Module: Page: Of: Section: Page: Of: Milling 2 3                        | Document No.       |              |
| ame:<br>ed ULTRA FINE Dead Sea Minerals (salts)                                         | Lot Code: 20101AUM | M            |

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Manufacturing Batch Record

Date of Manufacture: February 1, 2001

| and record:  and record:  GROSS: //O Lb  TARE: -2 Lb  NET WEIGHT: //O S Lb  110.0 Lb  110.0 Lb  ield limits are 97-103%. If outside this range, notify supervisor.  PHASE IV. COMPLETED | Performed By: Verified By:                   |             |    |     |               |                     | L,                                                                        | SW - SW               |          |                                         | ST SM |                                    | Lot Code: 20101AUM                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|-------------|----|-----|---------------|---------------------|---------------------------------------------------------------------------|-----------------------|----------|-----------------------------------------|-------|------------------------------------|-----------------------------------------------|
|                                                                                                                                                                                         | BULK MILLING-cont'd  Reconciliation: Grade 2 | GROSS: [10] | 7/ | 801 | x 100 = 98.18 | Lb) = Milling Loss: | NOTE: Yield limits are 97-103%. If outside this range, notify supervisor. | PHASE IV. COMPLETEDV. | Sampling | a. Submit two four ounce samples to QA. |       | Module: Page: Of: Section: Page: O | lame: ed ULTRA FINE Dead Sea Minerals (salts) |

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### DEAD SEA WORKS LTD

Polash House \* P.O.Box 75 \* Beer-Sheva 84100, Israel Tel. (972-7) 646 5347 \* Fax. (972-7) 628 0533 E-mail:chemerket@dsw.co.ll

**Marketing Division Chemical Products** 



באר-שבע 100 אבר בית האשלג 07-646 5347 .50 07-628 0533 .OPS

אגף שיווק למוצרים כימיים

January 2000

### DEAD SEA BATH SALTS

### Typical Analysis

| Components               | Formula           | Typical | Range       |  |  |
|--------------------------|-------------------|---------|-------------|--|--|
|                          |                   |         |             |  |  |
| Magnesium Chloride       | MgCl <sub>2</sub> | 33.3    | 31.0 - 35.0 |  |  |
| Potassium Chloride       | KCl               | 24.3    | 20.0 - 28.0 |  |  |
| Sødium Chloride          | NaCl              | 5.5     | 3.0 - 8.0   |  |  |
| Calcium Chloride         | CaCl <sub>2</sub> | 0.2     | 0.1 - 0.5   |  |  |
| Bromide                  | Br'               | 0.5     | 0.3 - 0.6   |  |  |
| Sulphates                | SO <sub>4</sub> " | 0.15    | 0.05- 0.2   |  |  |
| Insolubles               |                   | 0.03    | 0 - 0.3     |  |  |
| Water of Crystallization | n                 | 36.4    | 32.0 - 40.0 |  |  |

### Screen Analysis

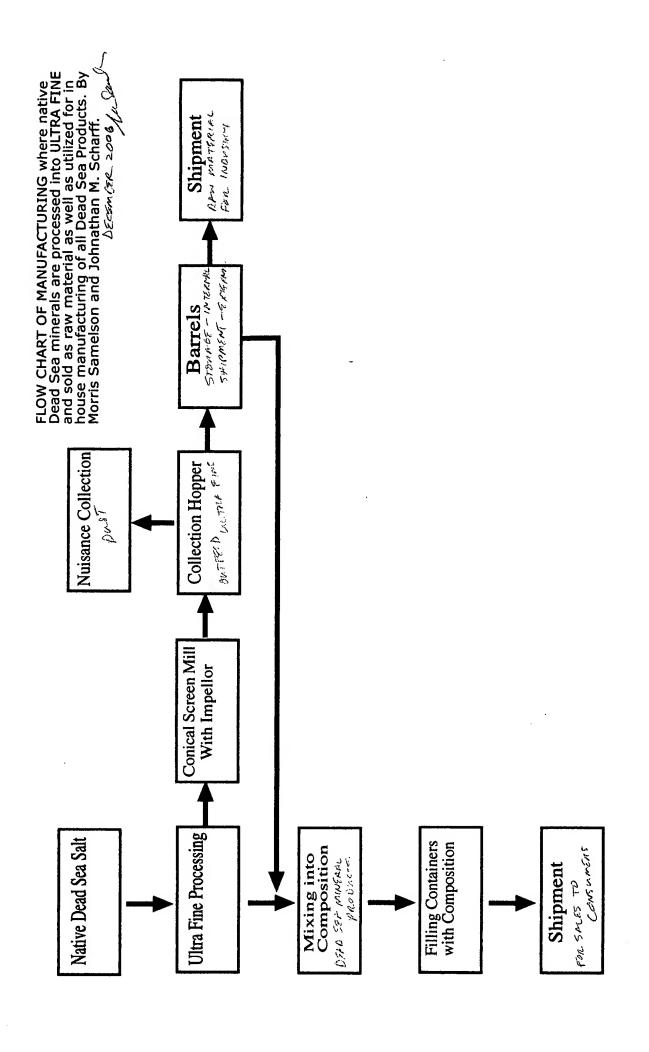
Fine Grade 90% < 10 mesh 90% < 1.7 mm

Coarse Grade > 90% between 5 & 10 mesh

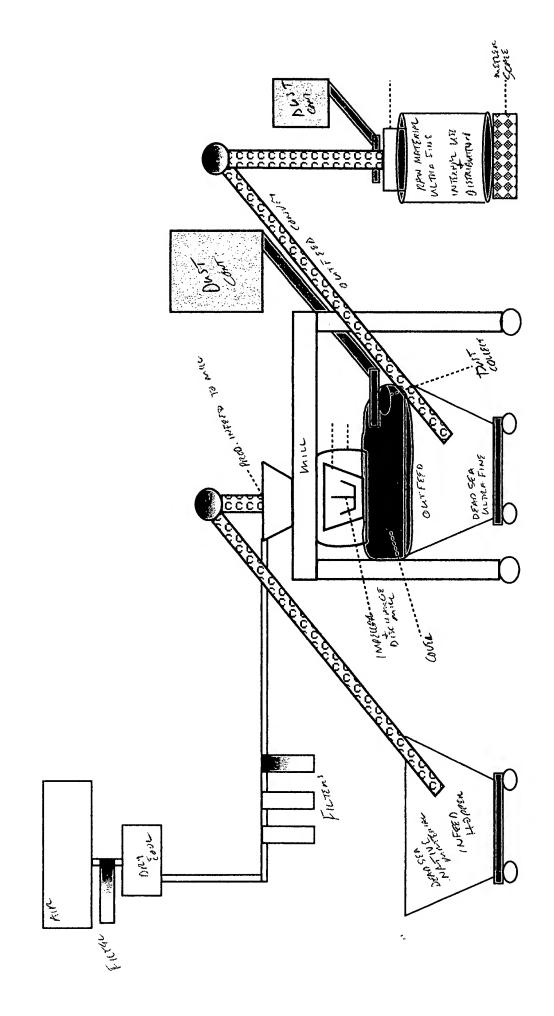
> 90% between 1.7& 4.0 mm

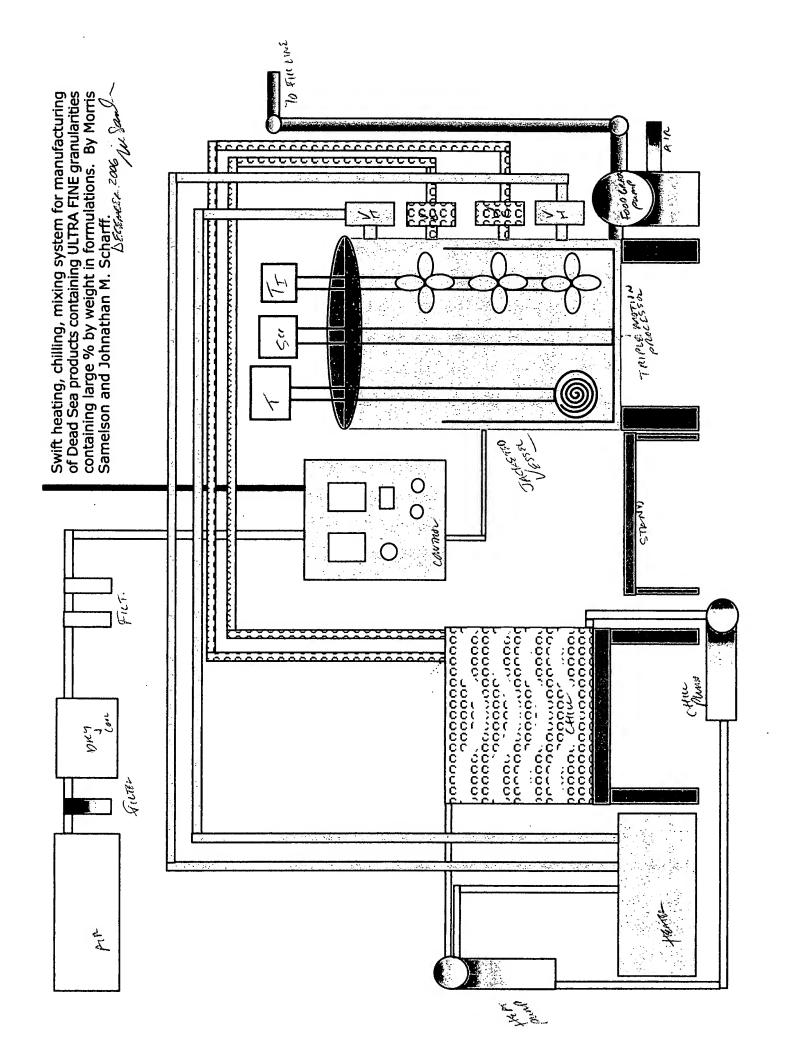
Alan Becker

Chief Process Engineer & Quality Control Manager Chemical Products Division



Milling system for processing Dead Sea Minerals to ULTRA FINE GRANULARITIES less than 1 mm. By Morris Samelson and Johnathan M. Scharff





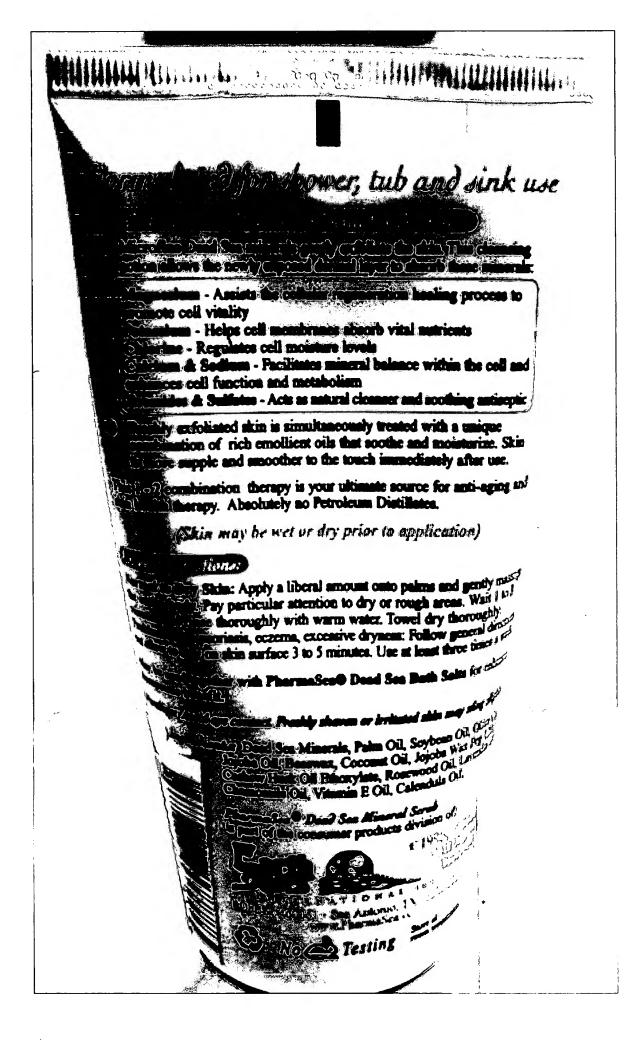
Formulated for shower, trib and sind

DharmaSea @ Dead Sea Mineral Serub work

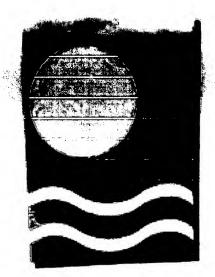
Microfine Dead Sea minerals gently cofoliate the abin The tation allows the newly exposed dennal layer to absent

Assists the cellular regeneration healing

somote cell vitality



Scrub



### g Pharma Sea°

Life Habanelog Minerals Harvestel
From Nature's Pharmacy

Advanced Dead Sea Therapy for ultimate skin care es bealth.

100% Natural

Exfoliates

Nourisbes

Rejuvenates
Not Weight = 5 of.

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